

Notice of Allowability

Application No.

10/709,196

Examiner

Leslie R. Deak

Applicant(s)

BAINBRIDGE ET AL.

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to after final amendment filed 23 October 2007.
2. ☒ The allowed claim(s) is/are 1-4, 6, 7, 10-20, 24, 26, 29-34, and 37-39.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Reasons for Allowance

1. Claims 1-4, 6, 7, 10-20, 24, 26, 29-34, and 37-39 are allowed.
2. The following is an examiner's statement of reasons for allowance: The prior art fails to disclose or suggest the method and apparatus claimed by applicant.

US 5,658,240 to Urdahl teaches the method of using donor-specific characteristics to generate parameters for an initial procedure order, but does not teach or fairly suggest the step of generating a list of acceptable donation procedures based on patient parameters and using that generated list to select an appropriate procedure for the patient, in combination with the other steps and limitations of the claims drawn to a blood component collection procedure.

US 7,072,769 to Fletcher-Haynes et al discloses the method and apparatus as claimed, but is unavailable as prior art, since it was filed (1 March 2001) before the effective priority date of the instant application (9 March 2001), and was commonly owned with the instantly claimed device and method at the time of invention, rendering the reference unavailable for use in a 35 USC 103 rejection.

US 6,602,179 to Headley discloses a blood processing method and apparatus that comprises the steps of delivering a replacement fluid and an anticoagulant in a single solution, but does not teach or fairly suggest the step of manipulating the flow rate of anticoagulant on its own. Headley also does not disclose or suggest the step of generating a list of acceptable donation procedures based on patient parameters and using that generated list to select an appropriate procedure for the patient, in

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combination with the other steps and limitations of the claims drawn to a blood component separation procedure.

With regard to applicant's claims 25-26 and 29-34 drawn to a system that performs the claimed method, applicant claims a "means for using a plurality of donor/patient characteristics to determine blood component capable of being collected from said donor/patient and for generating a list having a plurality of blood component collection options...."

Applicant's language in claim 25 appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for " or "step for; "
- (B) the "means for " or "step for " must be modified by functional language;
and
- (C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification.

In the specification, applicant defines the "means for....," as reproduced above, as a controller that performs the claimed function. Accordingly, the examiner is interpreting the "means for" passage to encompass such a controller and its equivalents. Equivalent structures may include

- a) those that perform the function specified in the claim,

- b) structures that are not excluded by any specific definition provided in the specification for an equivalent, or
- c) a structural equivalent of the corresponding element disclosed in the specification. See MPEP 2183.

While the prior art discloses several controllers that are capable of being programmed to perform the function claimed by applicant, the prior art does not teach or suggest such a programmed controller. Since the prior art controllers do not perform the function claimed by applicant, they fail the first prong of the test set forth in MPEP 2183, and do not qualify as equivalent structures. Accordingly, the instantly claimed device is patentable over the prior art.

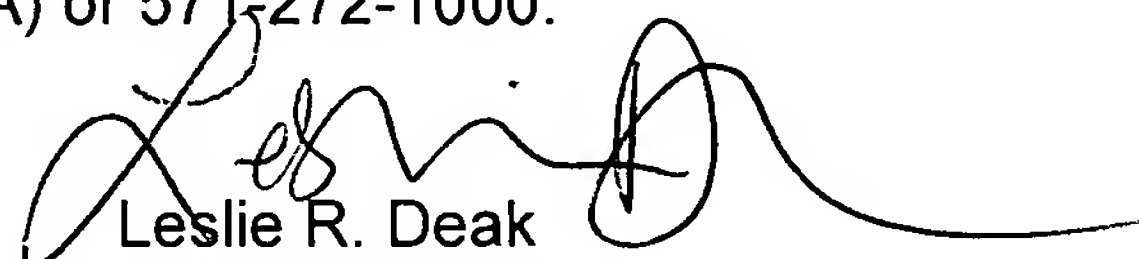
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
5 November 2007